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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,710	06/13/2001	Stavroula Kousteni	ANA 1007 US	5533

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EXAMINER	
BASI, NIRMAL SINGH	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/880,710	KOUSTENI ET AL.	
	Examiner	Art Unit	
	Basi Nirmal	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4 and 11-15, drawn to a method of inducing a nongenotropic effect of a steroid receptor comprising contacting a receptor with a compound that induces a nongenotropic effect, classified in class 514, subclass 2.

II. Claims 5-7, drawn to a method of inducing a genotropic effect of a steroid receptor, classified in class 514, subclass 2.

III. Claims 8-10, 16-36 drawn to a method of screening for a compound that will induce a nongenotropic effect of a steroid receptor by determining ability to activate a ligand-binding domain activated pathway, classified in class 436, subclass 63.

IV. Claims 8-10, 16-34 drawn to a method of screening for a compound that will induce a nongenotropic effect of a steroid receptor by determining ability to activate a DNA-binding domain activated pathway, classified in class 436, subclass 63.

V. Claim 37, drawn to a kit comprising cell line transfected with a steroid receptor report gene construct, classified in class 435, subclass 69.1.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have mutually exclusive effects, group I being

drawn to induction of nongenotropic effects and group II being drawn to induction of genotropic effects.

Inventions I and III or IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The invention of Group I induces an effect or treatment while that of Groups III or IV merely screens for an effect of a compound but does not apply said compound. The methods have different method steps and different goals.

Inventions of Groups II and III or IV are unrelated, being drawn to mutually exclusive goals, II being drawn to a method of inducing a genotropic effect and group III or IV being drawn to a method of screening for compounds having a mutually exclusive effect.

Inventions of Groups III and IV are unrelated, being drawn to mutually exclusive goals with different method steps to reach said goals. Group III is drawn to identifying a compound which activates through the ligand binding domain not through the DNA binding domain, while Group IV is the opposite.

Because these inventions are distinct for the reasons given above and the search required for any single Group is not required and not coextensive for any other Group, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: Each of Groups I-V encompasses distinct steroid receptors of which applicant is required to elect one for examination purposes, selected from:

1) progesterone receptor

2) glucocorticoid receptor

3) mineralcorticoid receptor

4) retinoic acid receptor

5) bile acid receptor

6) thyroid receptor

7) farnesoid X receptor

8) liver X receptor

9) ecdysone receptor

10) COUP-TF receptor

11) estrogen receptor

12) Vitamin D receptor

13) PPAR receptor

14) preganane X receptor

Should applicant elect Group I, applicant is further requested to elect a species of selective compound as follows:

a) a compound that induces a nongenotropic effect other than those mediated by the activation of extracellular regulated kinase.

b) a compound that induces a nongenotropic effect for use other than in bone loss or to increase bone mass

c) a compound that induces a nongenotropic effect other than an estrogen or androgen containing a cyclopentanopherhydrophenanthrene nucleus.

Should applicant elect Groups III or IV, applicant is further required to elect a nongenotropic acitivity to be measured as follows:

i) apoptosis

ii) modulation of signal transduction

iii) modulation of a second messenger

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Basi Nirmal whose telephone number is 703-308-9435. The examiner can normally be reached on 1030-800.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eyler Yvonne can be reached on 703-308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

Yvonne Eyler

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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